

# EPA REGULATORY DEVELOPMENT PROCESS

## ISSUE SUMMARY

- EPA uses an established internal process (the Action Development Process or ADP) to ensure the consistent development of rules and other agency actions. The process facilitates cross-agency participation where appropriate and gives senior management multiple opportunities to provide guidance and direction to staff at key points during the process.
- The ADP, managed by the Office of Policy, emphasizes collaboration among EPA offices and sound scientific, economic, legal, and policy analyses. The ADP also ensures that key issues are presented to senior management at the appropriate stages in the action development.
- As part of this process, EPA shares significant regulatory actions with the Office of Management and Budget (OMB) for interagency review and comment under Executive Order 12866.

## BACKGROUND

Developing environmental regulations is one of main ways EPA achieves its mission of protecting human health and the environment. The EPA typically prepares and releases to the public between 500-600 proposed and final actions a year that define the technical and operational details of environmental programs.

### Action Development Process

Recognizing that actions can differ greatly in their scope, cost, complexity, and impacts, each action is initially assigned a tier that determines the level of the decision maker for the action and the degree of cross-agency involvement the action may require. For example, Tier 1 actions are the most complex actions and may involve precedent setting issues, have high costs and/or benefits, may have a high level of external interest, and/or significantly impact the work of more than one agency program. For these reasons, the Administrator is typically the decision maker for all Tier 1 actions. In contrast, Tier 3 actions are developed by and impact only a single EPA office, are typically routine or non-controversial, and do not require extensive cross-agency interactions, while Tier 2 actions fall somewhere in between. The Administrator generally signs roughly 120 actions each year, approximately 60% of which are from the Office of Air and Radiation. Typically, approximately 10% of the total actions each year are Tier 1 and 70% are Tier 3.

### Major Steps - Tier 1 and 2 Actions

Tier 1 and 2 actions are developed by an intra-agency workgroup with a lead National Program or Regional Office. The workgroup completes formal ADP milestones to ensure that senior management is involved early and provides guidance throughout the process. The major steps in the process are as follows:

1. **Early Guidance** – Discussion of a project plan that outlines what data will be collected, what preliminary options will be examined, how they will be analyzed, and which stakeholder groups will be consulted.
2. **Analytic Blueprint** – This is the workgroup's plan for conducting analyses to support action development, is informed by early guidance, and outlines how the workgroup will collect and analyze data and information to develop policy options.
3. **Options Selection** – Once options are analyzed, the decision maker will hold a workgroup meeting with senior managers from other participating offices to select a course of action. Options selection meetings give management the opportunity to review the major scientific and economic analyses the workgroup has prepared and direct the workgroup in how to complete the draft action.

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4. **Final Agency Review** – Once the action and any supporting analyses are developed, the lead office distributes the action to each National Program and Regional Office represented on the workgroup requesting their formal position on the package. If there are significant outstanding issues, the matter is elevated for resolution.

## Development of Tier 3 actions

Lead offices have more discretion and flexibility to decide the appropriate methods for developing Tier 3 actions; however, the process still requires the inclusion of all offices that may express an interest in participating in the ADP.

## Recent ADP Updates

Since designing the ADP almost 30 years ago, the agency has periodically made improvements to the process to encourage better planning and analysis and promote improved collaboration among offices and agencies. Several recent improvements include transitioning to digital signature for actions being published in the Federal Register, increasing early engagement and cross-agency participation, encouraging prompt elevation of issues, and using a standard waiver process to facilitate time-critical actions.

## Related Requirements

Rules issued by the agency must comply with various statutes and Executive Orders related to rulemakings. EPA typically addresses these in rule preambles. The most notable include:

- **Executive Orders 12866 and 13563** that define EPA's relationship with the Office of Management and Budget and lay out analytical and interagency procedural requirements for rulemakings.
- **Executive Order 13771** stipulates that for every new regulation issued, at least two existing regulations must be identified for repeal. Compliance with EO 13771 is measured by the number of deregulatory actions being at least two times the number of regulatory actions and meeting the annual cost savings goal.
- The **Regulatory Flexibility Act**, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), provides analytical and procedural requirements related to a rule's impact on small entities (primarily businesses) and requires EPA to work with OMB and the Small Business Administration's Office of Advocacy to consult directly with affected small entities if a rule has a "significant impact on a substantial number of small entities".
- **Executive Order 12898** requires EPA to identify and address disproportionate impacts from rules on minority and low-income populations.
- The **Paperwork Reduction Act** generally provides that every federal agency must obtain approval from OMB before using identical questions to collect information from 10 or more persons. Many EPA rules require information collection, which is managed by the EPA Office of Management Services.
- **Executive Order 13132** requires EPA consult with state and local officials or representative national organizations on certain rules that impact state or local governments or preempt state or local laws.

## OMB Review of Significant Actions

EPA works with OMB to determine in advance which actions OMB will determine to be "significant" regulatory actions requiring interagency review. Actions are generally determined to be significant" because they impose high costs or implicate a novel policy issue. OMB generally reviews nearly all of EPA's Tier 1 and Tier 2 actions and some Tier 3 actions. OMB reviews, on average, a total of approximately 50 actions per year.

When OMB review is necessary, EPA must submit the action to OMB using a dedicated database and address its comments, as well as those from other interagency reviewers. Actions that are under review can be viewed at [www.RegInfo.gov](http://www.RegInfo.gov). EPA is also required to docket the version of the action submitted to OMB for review and to identify substantive changes made during interagency review.

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## KEY EXTERNAL STAKEHOLDERS:

- ☒ Congress      ☒ Industry      ☒ States      ☒ Tribes      ☒ Media      ☒ Other Federal Agency  
☒ NGO      ☒ Local Governments      ☐ Other (name of stakeholder) \_\_\_\_\_

Most external stakeholders are generally not interested in the details of the regulatory development process itself; however, steps in the process do facilitate participation by other federal agencies (during interagency review) and external stakeholders (public comment period, SBREFA panels, federalism consultation). The media, Congress, and GAO can also become interested in the procedural details of specific high-profile rules.

## MOVING FORWARD:

The IT infrastructure that supports the action development in EPA is being updated and consolidated into a new system called EPA Action Management System (EAMS) that will be launched in FY 2021.

LEAD OFFICE/REGION: ORPM/REGION 9

OTHER KEY OFFICES/REGIONS: AO, NPM

All EPA offices and regions participate in the action development process.